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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/577,428

08/14/2006

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Q94528

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23373 7590 07/20/2009
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EXAMINER

EISEMAN, ADAM JARED

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

07/20/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/577,428	Applicant(s) RICHARD ET AL.	
	Examiner ADAM J. EISEMAN	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is responsive to the applicant's amendments and arguments/remarks filed on 4/23/2009.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

3. The applicant's submitted substitute specification has been received and has been placed in the record on file.

Claim Objections

4. The previously held claim objections have been withdrawn in view of the applicant's amendments.

Claim Rejections - 35 USC § 112

5. The previously held 35 USC § 112 rejections have been withdrawn in view of the applicant's amendments.

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1-4, 11, 15-17 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutton (US 7,179,232) in view of Twersky (US 4,445,788).

Sutton discloses a bone marrow extraction device comprising:

- A grip zone (element 52)

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- A needle (element 24) presenting at least one side orifice (element 26)
- The device characterized in that the needle is connected to a needle holder (enlarged proximal portion of inner needle; figure 3), and in that a protective sleeve (outer cannula, element 16) surrounds at least a part of said needle (see figure 1-3), said protective sleeve being mounted to move relative to said needle between a closed position the side orifice and an open position of the side orifice (column 5, lines 16-28)
- A mating arrangement between the needle holder and the base of the sheath to connect the inner and outer cannula and permit rotational movement of the cannula so as to selectively align the orifices of the cannula between the open and closed position (column 4, line 56 to column 5, line 9)

However, Sutton does not disclose fastener means on the protective sleeve to engage reception means on the needle holder so as to hold the protective sleeve in the open or closed position.

Twersky teaches the use of a detent mechanism (element 29) used to lock a sheath into either an open position where apertures in the sheath aligned with inner apertures or to a closed position where the sheath shields the apertures (column 3, lines 9-21).

Regarding claims 1-4, 11, and 15-17; Sutton teaches the use of indicia (elements 58) on the sheath handle and needle holder which place the apertures in an open position when aligned and a closed position when misaligned (column 6, lines 48-62). It

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would have been obvious to one of ordinary skill in the art at the time of the invention to modify Sutton to use a locking/fastening mechanism as taught by Twersky for holding the sheath and needle apertures in an open or closed position in order to provide the user with the ability to quickly and assuredly move the orifice between the open and closed positions (as suggested by Sutton's alignment indicia which indicate open and closed positions).

Further regarding claim 2; Sutton discloses that the outer cannula is mounted to turn about the inner cannula.

Further regarding claim 3; Sutton discloses that the sheath includes at least one side opening (element 20) that is positioned facing the orifice of the needle in the open position (column 5, lines 16-28).

Further regarding claim 4; Sutton discloses that the handle part of the sheath (element 32) is used for mating the sheath to the needle.

Further regarding claim 11 and 15-16; Sutton discloses that the device can be used to extract bone marrow.

Further regarding claims 15-17; Sutton discloses an outlet port (element 54) connected to the needle for connection to any well known medical device for providing suction (column 6, lines 40-47). Furthermore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use a vacuum pump as the suction means as they are a well known device for providing suction and that pedals are well known actuators for actuating medical devices.

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Further regarding claim 23; it would have been obvious to one of ordinary skill in the art at the time of the invention to provide the device in sterile packaging as it is well known in the art of medical devices to use sterile packaging to prevent infection and disease.

8. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutton in view of Twersky as applied to claim 4 above, and further in view of Juhn (US 4,641,663).

The Sutton/Twersky combination is described in the rejection of claims 4 above; however it does not disclose that the fastener means are a pivotally mounted claw that presents a manual actuation surface and projection.

Juhn discloses a fastening means that is a pivotally mounted claw-like fastener (element 67) that presents an actuation surface (element 74) and a projection (element 73) which locks an inner cannula into a position (figures 5-8).

Regarding claims 5-6; it would have been obvious to one of ordinary skill in the arts at the time of the invention to substitute the fastening/locking means of the Sutton/Twersky combination with Juhn's claw fastening mean in order to provide an actuation surface for easier connection and locking.

Further regarding claim 6; it would have been obvious to one of ordinary skill in the art that the use of Juhn's locking means requires a groove or ledge for receiving the projection (element 73) in order for the fastening means to hold.

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9. Claims 7 and 12-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutton in view of Twersky as applied to claim 1 and 11 above, and further in view of Shapira (US 6,110,176).

The Sutton/Twersky combination is described in the rejection of claims 1 and 11 above; however it does not disclose a mixing chamber with an inlet and outlet port; providing an anticoagulant to the inlet channel; or connecting the outlet channel to a bone marrow collection vessel.

Shapira teaches a system and method for extracting bone marrow comprising: extracting bone marrow using the bone marrow extraction needle (element 85); mixing the extracted bone marrow with an anticoagulant solution; and transferring the mixed bone marrow solution to a collection chamber (column 8, lines 40-59). Furthermore, Shapira teaches that the solution can be mixed with the bone marrow before being transferred to the collecting means (column 8, lines 54-59).

Regarding claims 7-10 and 12-19; Shapira teaches the method of extracting bone marrow, mixing a solution with bone marrow, and transferring the mixed solution to a collection chamber but does not disclose the specifics of the apparatus used to perform extraction/mixing operation. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the Sutton/Twersky combination as the bone marrow extraction needle used in Shapira's method as simple substitution of one known element with another.

Further regarding claim 7-10 and 12-19; Shapira discloses a mixing chamber in the bone marrow extraction unit (see figure 4; mixing chamber being the area where the

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infusion fluid from the inlet port, the bone marrow, and outlet port meet in the hollow area of the extraction device). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Sutton/Twersky combination to include a mixing chamber where mixing of the infusion fluid and bone marrow occurs having an inlet port for the infused solution and an outlet port for transferring the mixed bone marrow/infusion solution to the collection chamber as taught by Shapira (figure 4; column 8, lines 40-59). Furthermore, it would have been obvious to one of ordinary skill in the art to include this mixing chamber anywhere in the extraction device as taught by Shapira where the space is in fluid communication with the biopsy site, inlet port and outlet port but before the collection chamber, including in the needle holder, in the handle, or as an insert to the Sutton/Twersky bone marrow extraction needle. It would have been obvious to try as choosing from a finite number of predictable solutions with reasonable expectation of success.

Further regarding claim 13; Shapira discloses use of an anticoagulant infused into the bone marrow mixing chamber. It would have been obvious to one of ordinary skill in the art that a Sutton/Twersky/Shapira combination would have an inlet channel to infuse the anticoagulant into the mixing chamber.

Further regarding claim 14; Shapira disclose extracting the mixed bone marrow to a collection chamber. It would have been obvious to one of ordinary skill in the art that a Sutton/Twersky/Shapira combination would have an outlet channel to extract the mixed bone marrow to the collection chamber.

Further regarding claim 15-17 and 19; Shapira discloses use of suction means to extract the bone marrow from the extraction site to the collection chamber. It would have been obvious to one of ordinary skill in the art at the time of the invention to use any well known suction means for providing suction to the needle including vacuum pumps, pedal actuated pumps, and timed pumps.

Further regarding claim 18; Shapiro discloses a mixing chamber having an inlet and outlet channel. It would have been obvious to one of ordinary skill in the art at the time of the invention to use any well known configuration of inlet and outlet channels for a mixing chamber to create effecting mixing including modifying the inlet valve to project the infused fluid into the mixing chamber towards the outlet channel to create a Venturi effect and effectively promote mixing.

10. Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutton in view of Twersky as applied to claim 1 above, and further in view of Morawski (US 2004/0010236).

The Sutton/Twersky combination is described in the rejection of claim 1 above; however it only discloses the use of the device for the extraction of bone marrow.

Morawski teaches that although a device is described as a bone marrow aspiration device, one of ordinary skill could use an aspiration needle to inject a fluid (abstract).

Regarding claims 20-22; it would have been obvious to one of ordinary skill in the art at the time of the invention to use the Sutton/Twersky combination to inject bone marrow into a patient as taught by Morawski.

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Further regarding claim 21-22; Sutton discloses that the needle can be connected to a medical syringe or similar medical device. It would have been obvious to one of ordinary skill in the art at the time of the invention that the syringe could be filled with bone marrow, thus acting as a bone marrow reservoir, and that the syringe could be electrically driven as automatic syringe drivers are well known in the art.

11. Claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutton in view of Twersky as applied to claim 1 above, and further in view of Gauthier (US 4,256,119).

The Sutton/Twersky combination is described above; however it does not disclose the fastening means as a pair of claws disposed diametrically opposite one another wherein the fastener means prevent radial force from being applied to the protective sheath.

Gauthier teaches a biopsy needle having fastening means comprising two diametrically opposed claws (elements 17 and 18) which align to fasten the biopsy needle into a set position (see figures 1-6).

Regarding claims 24-26; it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the fastening means of the Sutton/Twersky combination with Gauthier's fastening means to hold the biopsy needles in a set position (closed position) as simple substitution of one known element for another to obtain predictable results.

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Further regarding claim 25; Gauthier's fastener means prevent radial force from being applied to the protective sheath as Gauthier's fastener means provide for axial force application to hold the sheath in a set position.

Response to Amendment

12. The applicant's amendments and arguments/remarks have been fully considered but are moot in view of the new grounds of rejection.

The applicant's argument that Sutton teaches away from combination with Twersky is non persuasive. The applicant argues that Sutton's needle and protective sleeve are movable with respect to one another and that Sutton does not desire for the protective sleeve to be placed in a closed position. This is found to be non persuasive as Sutton discloses that the openings on the cannula shaft (element 24) are adapted to be selectively aligned with the openings of cannula shaft (element 16). Selective alignment of the openings of the cannula shaft inherently allows for the selective 'misalignment' (or closing) of the openings. Thus one of ordinary skill in the art at the time of the invention, would have motivation to provide means for enhancing the selective alignment of the openings, including that as taught by Twersky which would both provide a tactile feeling when the openings are alignment and opened or misaligned and closed and an indicator that to ensure the positioning of the cannula in relation to each other.

The applicant's argument that there is no motivation to combine Sutton and Twersky because they are different fields of endeavor (bone marrow biopsy and soil probes respectively) is found to be non persuasive. It is well known in the art that bone

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marrow sampling is a method of coring a material, thus one of ordinary skill in the art would have motivation to search any field regarding coring of a material using a needle or probe such as soil coring.

The applicant's argument that the Shapira fails to indicate that the mixing of the bone marrow and anticoagulant could be provided in the extracting apparatus and that there is no possible place to provide mixing in the apparatus is found to be non persuasive. Shapiro discloses a mixing chamber in an extraction apparatus wherein an infusion fluid is mixed with extracted bone marrow and subsequently extract to a collection chamber (see figure 4). Furthermore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Sutton/Twersky combination to include both an inlet port and an outlet port to the extraction needle as shown in Shapira.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ADAM J. EISEMAN whose telephone number is (571)270-3818. The examiner can normally be reached on Monday-Friday 9:00 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AE
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/A. J. E./

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Examiner, Art Unit 3736

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736